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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,953	07/29/2003	Rebecca E. Cahoon	BB1194 USCNT	8896

23906 7590 01/18/2005

E I DU PONT DE NEMOURS AND COMPANY
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EXAMINER

BUI, PHUONG T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/629,953	Applicant(s) CAHOON ET AL.	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's amendment and restriction election filed October 26, 2004. Applicant elected Group I and Invention B (SEQ ID NO:3 and 4) without traverse. Claims 24-35 are pending and are examined in the instant application. This restriction is made final.

Specification

2. Applicant is required to update the status of parent priority Application No. 09/743336 on the first line of the specification.

Claim Rejections - 35 USC 101 Utility

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 24-35 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. The claimed invention lacks substantial utility because Applicant does not teach how the claimed invention can be used to achieve a real-world use. Applicant indicated that SEQ ID NO:4 is a transcription factor-dependent coactivator and binds to both ssDNA and dsDNA (p. 1). While DNA transcription is important, it is unclear how Applicant's SEQ ID NO:4 should be used to affect DNA transcription in a manner that would be beneficial to the public and result in a useful outcome. Applicant described how PC4 transcriptional coactivator interacts with various complexes and how PC4 DNA-binding activity can be abolished (p. 1), but Applicant provided no guidance as to how the

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claimed polynucleotide should be used to affect these interactions and bindings in a useful manner. It is unclear whether SEQ ID NO:4 should be overexpressed, decreased or inhibited from expression to achieve a useful outcome, whatever that useful outcome may be. What gene(s) would be affected, and would manipulation of the expression of SEQ ID NO:4 ultimately results in a useful plant trait? It is apparent that further research is required before the claimed polynucleotide would be of benefit to the public. However, the courts have decided that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use lacks substantial utility.

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (Brenner v. Manson, 383 U.S. 519 (1966)).

Thus, while regulating DNA transcription would provide substantial benefit to the public, the claimed invention is not refined and developed to the point where specific benefit exists, as no guidance is provided as to how SEQ ID NO:3 should be used to alter any specified plant gene or trait. Accordingly, the claimed invention lacks substantial asserted utility.

Additionally, there is no well-established utility for SEQ ID NO:3 and a sequence encoding SEQ ID NO:4. SEQ ID NO:3 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed sequences lack utility (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112, first paragraph

5. Claims 24-35 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Additionally, claims 24-26 and 29-35 reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining transcriptional coactivator activity. Applicant provided no working example or further guidance as to which region(s) of SEQ ID NO:3 are conserved domains necessary for protein activity. While one skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated without undue experimentation. Accordingly, the claimed invention is not enabled.

6. Claims 24-26 and 29-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims reciting less than 100% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass transcriptional coactivators from other species

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which are not disclosed. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:3 isolated from *Oryza sativa*. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants and allelic variants of transcriptional coactivators of other *Oryza sativa* plants, or the structure of transcriptional coactivators from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 24-25 and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (Plant Journal, Vol. 6, No. 4, 1994, p. 615-624 (U)). Sasaki teaches a sequence which has 91% sequence identity with a sequence encoding SEQ ID NO:4 (Acc. No. D15350, Clone C0499), vector (p. 617, column 1, "Discussion"), recombinant DNA construct (p. 617, "Experimental Procedures"), method for transforming a cell (p. 618, first two lines), and cell (p. 618, line 2). Even though Sasaki was silent as to whether said nucleotide sequence would encode a polypeptide having

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transcriptional coactivator activity, this appears to be an inherent property of the polynucleotide sequence of Sasaki. Even if it were not, the full-length complement of the sequence of Sasaki is also encompassed by the claims. Accordingly, Sasaki anticipated the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 24-25 and 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki (Plant Journal, Vol. 6, No. 4, 1994, p. 615-624 (U)) as applied to claims 24-25 and 29-32 above, and further in view of Goodman (USPN 4956282 (A)). The teachings of Sasaki have been discussed above. Sasaki does not teach plant transformation or seed. Goodman teaches plant transformation with various heterologous polynucleotide sequences and transgenic seeds obtained therefrom. It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to transform a plant with the polynucleotide sequence of Sasaki for the purpose of protein expression, use the plant as a repository for the sequence of interest, or for the same reasons as Sasaki in transforming a bacterial cell. Bacterial cell and plant cell are alternative host cells which can be used without any surprising or unexpected results. Once stably transformed, the seed obtained therefrom would also

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contain the polynucleotide sequence. Thus, one skilled in the art would have been motivated to do so with a reasonable expectation of success.

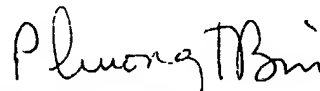
Remarks

11. No claim is allowed. SEQ ID NO:3 and a nucleotide sequence encoding SEQ ID NO:4 are free of the prior art.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Phuong T. Bui
Primary Examiner
Art Unit 1638

1/10/05